UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,560	08/16/2006	Klaus Abraham-Fuchs	32860-001073/US	8514

30596 7590 04/28/2011

HARNESS, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER	
FUELLING, MICHAEL	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
04/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcmailroom@hdp.com
siemensgroup@hdp.com
pshaddin@hdp.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/589,560
Filing Date: August 16, 2006
Appellant(s): ABRAHAM-FUCHS ET AL.

Donald J. Daley, Esq.
Reg. No. 34,313
For Appellants

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 11, 2011 appealing from the Office action mailed November 10, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Claims 1-23 currently are pending; are under Final rejection and are being appealed.

4) Status of Amendments After Final

The examiner has no comment on the appellants' statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellants' statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellants' brief.

(8) Evidence Relied Upon

Brimm et al. US Patent No. 5,072,383

Brown US Patent No. 6,168,563

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brimm et al., US Patent No. 5,072,383** (Brimm) in view of Brown, US Patent No. 6,168,563 (Brown).

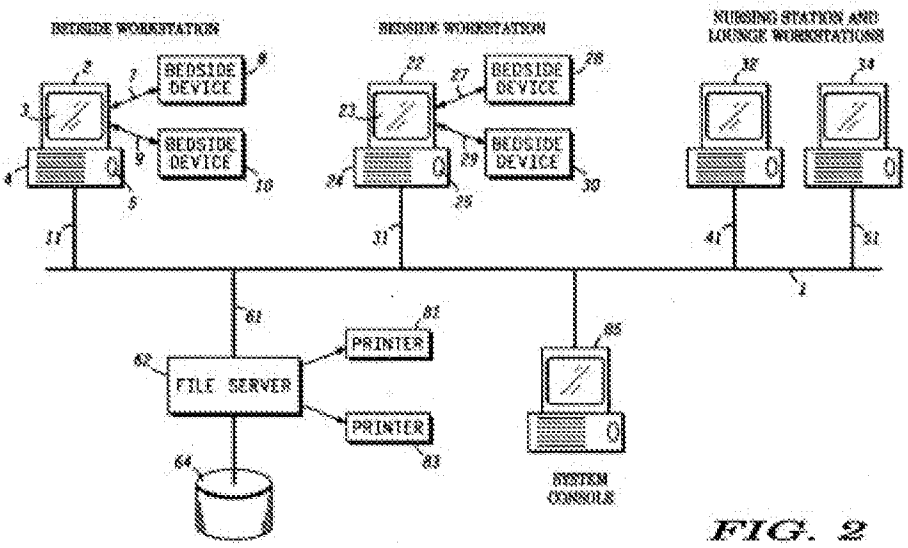


FIG. 2

As per **claim 1**:

Brimm does not use the term clinical study, however, Brimm is in the field of medical regimen, and a clinical study is a medical regimen.

Brimm teaches the concept of an electronic medical records system for sharing patient information between multiple different doctors monitoring multiple different medical regimen for the patient.

In particular, Brimm discloses:

- *storing on a memory, study-related data associated with a protocol of the clinical study* (C4, L10-20 “automated clinical records management”)*;*

- *storing, on the memory, patient-related data associated with the patient and the clinical study* (Abstract patient information system)*;*

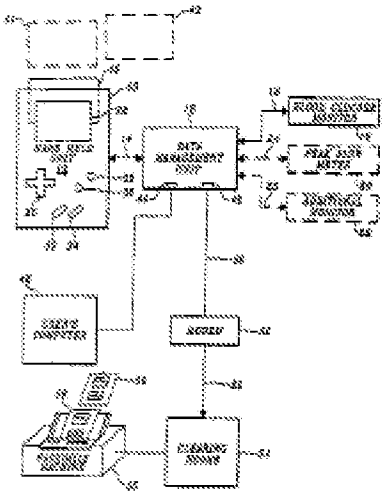
- *reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data* (Abstract physician and C4, L25 terminal unit with display means)*,*

- *wherein the memory is a computer readable storage medium* (C4, L25 “memory unit”).

Brimm might not appear to expressly disclose:

- *the memory is one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient.*

Brown discloses a portable memory device transported by the patient, which is a part of a data network, with “limited access” authorized by the patient (Abstract – apparatus is operated by the patient; Figs. 2 & 3 and 31 & 32 – networks). The networked portable device (**2026**) has a memory (**2080**).



Appellant described the way that they grant access is by a patient physically giving their family doctor a USB [0054].

The examiner finds the way that the device of Brown operates fairly reads upon appellants' claimed "limited access" because the device of Brown is controlled by the patient, thereby the patient decides whether another doctor may view the data which was placed on the device's memory by a first doctor (C29, L40 and C32, L35 - script programs).

Since each individual element and its function are shown in the prior art, albeit in separate references, the differences between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

One would have been motivated to make the substitution to improve monitoring the patient's compliance with the medical regimen.

Referring to claim 2, Brimm and Brown disclose all of the limitations of claim 1, and Brimm further discloses: *data* is *stored in the memory by a study doctor* (C9, L17 physician enters orders).

Alternatively, Brown discloses data is stored in the memory by a study doctor, as detailed above (C29, L40 and C32, L35 - script programs).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 3 and 11, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: another *doctor reads the data out from the memory before an interaction with the patient* (C5, L53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 4 and 12, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *data* is *stored in the memory with standardized structuring* (Fig. 10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 5 and 13, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *clear instructions to* another *doctor are stored as data* (C11, L25 creation of task list).

Referring to claims 6 and 14, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *data* is *assigned to various classes, and* another *doctor reads only information of one class out from the memory* (C9, L19 select from a list the type of information).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

As per **claim 7**:

The examiner notes that this system claim includes a method limitation in that it recites "*the limited access being authorized by the patient*."

The appellants have not provided a drawing for the claimed system as their Figs. 1 & 2 are flowcharts for the method.

Brimm does not use the term clinical study, however, Brimm is in the field of medical regimen, and a clinical study is a medical regimen.

Brimm teaches the concept of an electronic medical records system for sharing patient information between multiple different doctors monitoring multiple different medical regimen for the patient.

In particular, Brimm discloses:

- *a memory to store at least one of study-related and patient-related data* (C4, L10-20 "automated clinical records management"),

- *the memory being a computer-readable medium assigned to the patient* (C4, L25 "memory unit");

- *a data input device to input data being stored in the memory* (Abstract patient information system and Fig. 2); *and*

- *a data reading device to read the data out from the memory, the data reading device being accessible by a non-study doctor assigned to the patient* (Abstract physician and C4, L25 terminal unit with display means).

Brimm might not appear to expressly disclose:

- the memory being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient.

Brown discloses a portable memory device transported by the patient, which is a part of a data network, with "limited access" authorized by the patient (Abstract – apparatus is operated by the patient; Figs. 2 & 3 and 31 & 32 – networks). The networked portable device (**2026**) has a memory (**2080**).

Appellant described the way that they grant access is by a patient physically giving their family doctor a USB [0054].

The examiner finds the way that the device of Brown operates fairly reads upon appellants' claimed "limited access" because the device of Brown is controlled by the patient, thereby the patient decides whether another doctor may view the data which was placed on the device's memory by a first doctor (C29, L40 and C32, L35 - script programs).

Since each individual element and its function are shown in the prior art, albeit in separate references, the differences between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

One would have been motivated to make the substitution to improve monitoring the patient's compliance with the medical regimen.

Referring to claims 8 and 18, Brimm and Brown disclose all of the limitations of claims 7 and 17, respectively, and the memory of Brown is portable, as detailed above.

The portable device (**2026**) has a memory (**2080**).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 9 and 19, Brimm and Brown disclose all of the limitations of claims 7 and 17, respectively, and Brimm further discloses*: data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Alternatively, to the extent it can be shown the input and output devices of Brimm would not interface with the portable device of Brown, Brown discloses input and output devices (Fig. 15 **2090** I/O interface, **2028** monitoring device).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to substitute the input and output devices of Brown for such devices of Brimm, and the results would have been predictable.

Further, to the extent these claims are intended to be directed to more than one network, Brown discloses its portable devices are connected to more than one network (Figs. 2 & 3 and 31 & 32).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to include the multiple networks of Brown, and the results would have been predictable.

Referring to claims 10, 15, 16 and 20, Brimm and Brown disclose all of the limitations of claims 7, 8, 9 and 17, respectively, and Brimm further discloses: *the data reading device is portable* (**11** bedside workstation).

Alternatively, to the extent it can be shown the reading device of Brimm would not interface with the portable device of Brown, Brown discloses a reading device on the portable device (Fig. 15 **2064** display).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to substitute the portable memory and reading device(s) of Brown for such devices of Brimm, and the results would have been predictable.

As per **claim 17**:

The examiner notes that this system claim includes a method limitation in that it recites "*the limited access being authorized by the patient*."

The appellants have not provided a drawing for the claimed system as their Figs. 1 & 2 are flowcharts for the method.

It is being interpreted that the terms memory means and memory are being used interchangeably.

Brimm does not use the term clinical study, however, Brimm is in the field of medical regimen, and a clinical study is a medical regimen.

Brimm teaches the concept of an electronic medical records system for sharing patient information between multiple different doctors monitoring multiple different medical regimen for the patient.

In particular, Brimm discloses:

- a memory means for storing at least one of study-related and patient-related data (C4, L10-20 "automated clinical records management"),

- the memory means being assigned to the patient, the memory being a computer-readable medium assigned to the patient (C4, L25 "memory unit");

- input means for storing data in the memory means (Abstract patient information system and Fig. 2); *and*

- reading means for reading the data from the memory means, the reading means being accessible by a non-study doctor assigned to the patient (Abstract physician and C4, L25 terminal unit with display means).

Brimm might not appear to expressly disclose:

- the memory means being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient.

Brown discloses a portable memory device transported by the patient, which is a part of a data network, with "limited access" authorized by the patient (Abstract – apparatus is operated by the patient; Figs. 2 & 3 and 31 & 32 – networks). The networked portable device (**2026**) has a memory (**2080**).

Appellant described the way that they grant access is by a patient physically giving their family doctor a USB [0054].

The examiner finds the way that the device of Brown operates fairly reads upon appellants' claimed "limited access" because the device of Brown is controlled by the patient, thereby the patient decides whether another doctor may view the data which was placed on the device's memory by a first doctor (C29, L40 and C32, L35 - script programs).

Since each individual element and its function are shown in the prior art, albeit in separate references, the differences between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

One would have been motivated to make the substitution to improve monitoring the patient's compliance with the medical regimen.

Referring to claim 21, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: another *doctor is a doctor who is at least one of not associated to the clinical study and external to the clinical study* (Abstract physician).

Referring to claim 22, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: *the clinical study is conducted to test at least one of medicaments, methods of surgical intervention, therapies, and diagnostic devices* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 23, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: *displaying, by the computer, at least one of the study-related and the patient- related data to* another *doctor device* (C4, L25 terminal unit with display means).

(10) Response to Argument

The sole basis for appellants' appeal to the Board for reconsideration is that appellants' contend that a medical regimen does not fairly read upon their claimed clinical study. Appellants' written description does not command that a clinical study is not a medical regimen. Page 1 of appellants' written description recites:

> "Clinical studies are commissioned and carried out by various backers or sponsors such as pharmaceutical companies, clinics or state institutions. For example, new medicaments, methods for surgical intervention, therapies or diagnostic devices are tested on patients. The aim is often approval of the tested product before an approval authority." (emphasis added)

It is the examiner's opinion that the appellants' Brief does not accurately represent this matter. On page 3 of appellants' Brief, their counsel suggests that the approval authority could be the US Food and Drug Administration (FDA). As can be seen, appellants' claims and its written description are devoid of any reference to the FDA or Title 21 of the US Code of Federal Regulations (CFR). This is yet another example of appellants' efforts to continually redefine the term clinical study throughout the prosecution history.

Appellants' clinical study can read on a wide array of activities, such as a physician recommending a supplement to a patient, or prescribing a commercially available drug for an off-label use. The approval authority could be a hospital committee that selects new equipment, and the 'test' of dependent claim 22 could be calibration or maintenance of medical equipment.

The examiner also respectfully submits that appellants' arguments are not commensurate with the scope of the claims. For example, for claim 6, the appellants' criticize Brimm on page 22 of their Brief by stating: "Brimm does not disclose the selection of medications from different classes of medications." Claim 6 has nothing to do with selecting different classes of medications. Moreover, claim 6 does not involve any kind of selection. It simply involves reading different classes / types of data and Brimm discloses multiple types of medical data.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/M. F./
Examiner, Art Unit 3626

Conferee:

/Robert Morgan/
Supervisory Patent Examiner, Art Unit 3626

Vincent Millin /vm/

Appeals Practice Specialist